

# Compliance Guidance

## **The Mammography Quality Standards Act Final Regulations Document #2**

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**U.S. Department Of Health And Human Services  
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Center for Devices and Radiological Health**

**Inspection Support Branch  
Division of Mammography Quality  
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Office of Health and Industry Programs**

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# **Preface**

## **Public Comment**

Comments and suggestions may be submitted at any time for Agency consideration to Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Finder at 301-594-3332.

## **Additional Copies**

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# **Compliance Guidance<sup>1</sup>**

## **The Mammography Quality Standards Act**

### **Final Regulations Document #2**

#### **Background**

The Mammography Quality Standards Act (MQSA) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565) which, under MQSA, previously regulated mammography facilities. This document addresses new questions that FDA has received since the publication of "Compliance Guidance, The Mammography Quality Standards Act Final Regulations" on August 27, 1998.

The FDA is planning a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing written materials to the public. The currently available written documents include a quarterly newsletter *Mammography Matters*, and an Internet home page (<http://www.fda.gov/cdrh/mammography>) containing all previously issued guidance, including the latest edition of "*Preparing for the MQSA Inspection*."

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<sup>1</sup> This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

## **Introduction**

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations. This guidance uses a question-and-answer format to provide information about how FDA will implement its mammography program under the final regulations and the MQSA.

Under its own authority, a state may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the state or local authorities regarding their requirements.

## **Inspections - General**

Question: What do the various inspection citation levels mean?

Answer: When FDA designed the MQSA inspection program, we realized that some inspection findings would have a greater impact on the quality of mammography than others. For this reason, FDA adopted different levels of severity (or significance) for inspection findings.

There are three possible levels of findings resulting from an MQSA inspection. They range from Level 1 (representing the most serious noncompliances with MQSA standards) to Level 3 (representing minor deviations from MQSA standards).

A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

A Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility.

A Level 3 finding indicates that the facility's performance is generally satisfactory. However, the inspection did show one or more minor deviations from MQSA standards.

If there are no findings, the inspection report will note "No Findings."

If any findings have not been corrected or have recurred since a facility's last MQSA inspection, they are identified as "Repeat Findings."

## Definitions

### 21 CFR 900.2(z)

*Mammographic Modality means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film and xeromammography.*

Question: Are spot compression, magnification, and implant imaging considered mammographic modalities?

Answer: No. A mammographic modality is a technology for radiography of the breast, such as screen-film mammography and xeromammography. Spot compression and magnification are techniques used with a mammographic modality, but are not to be considered separate mammographic modalities in and of themselves. Implant imaging represents an application of a mammographic modality to patients with breast implants.

Question: Are stereotactic biopsy, needle localization, and ductography considered mammographic modalities?

Answer: No. A mammographic modality means a technology for radiography of the breast. All of the above refer to interventional procedures in the breast, as opposed to mammographic modalities of the breast. They are currently exempted from the definition of mammography and, therefore, the requirements of the final regulations.

Question: Are ultrasound, magnetic resonance imaging (MRI), and nuclear medicine studies of the breast considered mammographic modalities?

Answer: No. A mammographic modality means a technology for radiography of the breast. All of the above refer to non-radiographic procedures and are not regulated under MQSA.

### 21 CFR 900.2(oo)

*Qualified instructor means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of section 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.*

Question: What are examples of individuals qualified to provide continuing education?

Answer: An individual providing continuing education must have adequate training and experience that prepares him or her to carry out specified training assignments. MQSA qualified interpreting physicians, radiologic technologists, or medical physicists are considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be considered qualified

to provide continuing education training to meet the regulations include, but are not limited to: instructors in a post-high school training institution, manufacturer's representatives, and individuals providing education in approved CME/CEU courses.

## **21 CFR 900.2(xx)**

*Traceable to a national standard means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within  $\pm$  3 percent of the national standard in the mammography energy range.*

Question: If a calibration laboratory that failed its last test has carried out corrective actions that it believes will now allow it to pass, will any of the air kerma instrument calibrations provided by the laboratory during the re-testing process be acceptable toward meeting the MQSA requirement?

Answer: No. Once a proficiency test has been failed and until the calibration laboratory has passed a new test, the laboratory's calibrations lack sufficient validity to provide assurance that the air kerma instrument meets the requirement.

Question: If NIST is unable, for any reason, to conduct a proficiency test for a calibration laboratory before the laboratory's 2 year expiration date, are the laboratory's calibrations provided between the expiration date and the date of passing the proficiency test acceptable?

Answer: It depends upon how promptly the calibration laboratory fulfilled its responsibilities during the test process and whether the laboratory ever successfully completed a proficiency test before. FDA will generally view the laboratory as having adequately fulfilled these responsibilities if it contacted NIST at least 60 days in advance of the expiration date to request a proficiency test for mammography calibrations and if it promptly performed its part of the calibration process when requested by NIST. If the laboratory takes these actions and NIST is unable to complete the test before the expiration date, then FDA will generally accept the validity of calibrations performed for 60 days after the expiration date, unless the laboratory is notified during that 60 day period that the test failed. If NIST still has not been able to complete the proficiency test by the end of these extra 60 days, the situation will be reviewed by FDA on a case by case basis to determine if additional time can be granted without unduly jeopardizing the public health. Note that a laboratory that has not completed its first proficiency test cannot be used to calibrate air kerma instruments used to meet the MQSA requirements.

Question: What if the laboratory continues to provide mammography calibration services during these 60 days, but then is informed that it has failed the proficiency test. Will the physicists who had their instruments calibrated during that period have to have them recalibrated? Will they have to resurvey any facilities that they might have surveyed during that period?

Answer: Yes to both questions, but only in a worst case scenario. FDA believes that this combination of events will occur very rarely. If it does occur, the situation will be reviewed on a case by case basis



by FDA to determine what actions are needed to protect the public health. If the magnitude of the test failure is small, indicating that the error that might be introduced into the calibration and thus into the survey results is small, it may be sufficient to alert the physicist to incorporate this error into his/her determinations of whether the dose regulations were met by the facility. The larger the magnitude of the failure, the more extensive will be the corrective actions. In the worst cases, a new calibration and new surveys may be requested or required by the corrective action plan.

Question: If a calibration laboratory met the proficiency test requirement in the final regulations before April 28, 1999 (the effective date of the final regulations), will that test "count" after April 28, 1999? Similarly, if an air kerma measuring instrument was calibrated in accordance with the final regulations before April 28, 1999, will that calibration "count" after April 28, 1999?

Answer: Yes, to both questions, so long as the permitted maximum time periods are not exceeded. If the proficiency test or calibration was successfully completed before April 28, 1999, in accordance with the terms of the final regulations, the test or calibration will not have to be repeated simply because the new regulations have become effective. The repetition of the proficiency test can wait until up to two years after the last test and the repetition of the calibration can wait until up to two years after the last calibration or until after the next repair, whichever comes first.

## **Personnel - General**

### **21 CFR 900.12(a)**

*Personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:*

Question: Are there any MQSA requirements for personnel performing any interventional mammographic procedure (e.g., needle localization, stereotactic biopsy, galactography)?

Answer: Currently, there are no MQSA requirements for personnel performing interventional mammographic procedures.

Question: Can experience obtained in a foreign country count towards meeting the continuing experience requirement?

Answer: No, with one exception. Only experience obtained in facilities or programs under the jurisdiction of, or recognized by, MQSA can be used to meet the continuing experience requirement. Therefore, experience obtained at MQSA certified facilities in foreign countries (e.g. US military facilities) is also acceptable.

Question: Can experience obtained in a Veterans Administration (VA) facility count towards meeting the continuing experience requirement?

Answer: Yes. Experience obtained in VA facilities can be used to meet the continuing experience requirement. VA facilities are recognized by MQSA in that they operate under rules that are substantially equivalent to MQSA, are accredited by FDA approved accreditation bodies, and undergo annual inspections performed by MQSA inspectors.

Question: Are there any MQSA qualifications related to the people providing general servicing of the mammography equipment?

Answer: No. However, the facility should only use people who are knowledgeable in the general servicing of mammography equipment because, under MQSA, the facility is ultimately responsible for the performance of its equipment.

Question: Are in-service training programs acceptable under the final regulations?

Answer: Yes, in-service training programs (training conducted within facilities specifically for facility staff) can be accepted under the final regulations. However, different types of training are required by the regulations and each type of training has specific requirements that must be met. When considering in-service training to meet specific requirements, the appropriate sections of the regulations should be checked to assure the training meets the requirements for that type of training.

Question: How will the counting periods for continuing education relating to new mammographic modalities be synchronized with the general continuing education requirement?

Answer: Compliance with this requirement will be assessed for each individual during the first facility inspection performed after all of the following date benchmarks have taken place:

1. June 30, 2002, or
2. The third anniversary of the end date of the calendar quarter in which he or she met their initial requirements, or
3. The third anniversary date after he or she began using the new mammographic modality.

The 36-month counting periods for both the general and the new mammographic modality continuing education requirements will be identical from the beginning. Any portion of the initial 8 hours of training in the new mammographic modality falling within this 36 months can be counted towards meeting both the general continuing education and the new modality continuing education requirement while still counting toward the initial new modality training requirement.

Question: We use only one mammographic modality (screen-film) at our facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?

Answer: Yes, if you are an interpreting physician or a radiologic technologist. FDA permits training in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each modality used by an interpreting physician or radiologic technologist. If screen-film is one, or the

only, modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen.

In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. The documentation must thus show that some of the 15 hours was related to screen-film mammography.

While facilities (and their personnel) will not have to provide documentation of **mammographic modality** specific continuing education until June 30, 2002, at the earliest, facilities can be cited for failure to meet this requirement after that date. Therefore, personnel should begin collecting such documentation as of 4/28/99.

FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not breakdown the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend. If needed, these agendas will allow personnel to use the **limited attestation policy** to document the amount of CME/CEU earned in each mammographic modality.

## Interpreting Physician

### 21 CFR 900.12(a)(1)(i)(B)(2)

*Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section.*

Question: During my residency I had 3 months of a combined chest/mammography rotation. Can I count all 3 months toward meeting the initial requirement?

Answer: No. Only that documented portion of a combined mammography/non-mammography rotation that directly relates to the regulated areas of mammography may count toward meeting the initial requirement for qualifying as an interpreting physician. The regulations stipulate that documentation of such formal training is necessary. In the example above, if half of each day of the rotation was spent in mammography and the other half in chest, a total of 1½ months would count toward meeting the requirement.

### 21 CFR 900.12(a)(1)(i)(C)

*Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy,*

*pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.*

**21 CFR 900.12(a)(1)(ii)(B)**

*Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.*

Question: I am an interpreting physician who attended a technologist's mammography training course and was awarded category A credit. The regulations say my CME must be category I. Can I use category A credit toward meeting the requirement?

Answer: No, because the Accreditation Council for Continuing Medical Education (ACCME) does not accept the American Registry of Radiologic Technologist's category A credit as counting toward its category I credit. While ACCME will accept category A credit as equivalent to category II credit, category II credit is not acceptable for meeting the interpreting physician's initial (with the exception that category II credit is acceptable toward meeting the 8 hour new mammographic modality training requirement) or continuing MQSA education requirements.

## ACCEPTABLE DOCUMENTS FOR INTERPRETING PHYSICIANS

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State License	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>
Board Certification (ABR, AOBR, or RCPSC)	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>
Formal Training (2 months-interim regs) (3 months-final regs)	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>
Initial Medical Education (40 hours-interim regs) (60 hours/15 in last 3 years-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter from residency program</li> <li>3. CME certificates</li> <li>4. Letter or other document confirming in-house or formal training</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter from residency program</li> <li>2. CME certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter from residency program</li> <li>2. CME certificates</li> <li>3. Letter or other document confirming in-house or formal training (Category I)</li> </ol>
Initial Experience (240) (any 6 month period-interim regs) (last 6 month vs 6 month in last 2 years of residency-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter or other document from residency or training program or mammography facility</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from residency or training program or mammography facility – done under direct supervision</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from residency or training program or mammography facility – done under direct supervision</li> </ol>
Initial Mammographic Modality Specific Training-8 hours-final regs	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Mammography Modality Specific CME certificates (Category I or II)</li> <li>3. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CME granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME certificates (Category I or II)</li> <li>2. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME certificates (Category I or II)</li> <li>2. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Experience (960/24 months)	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from residency or training program or mammography facility</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from residency or training program or mammography facility</li> </ol>
Continuing Education (15 CME/36 months-interim regs) (15 Category I CME/36 months-final regs)	N/A	<ol style="list-style-type: none"> <li>1. CME certificates (Category I or II)</li> <li>2. Confirming letters from CME granting organizations</li> <li>3. Letters, certificates or other documents from manufacturers' training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CME certificates (Category I)</li> <li>2. Confirming letters from CME granting organizations</li> </ol>
Continuing Mammographic Modality Specific Education-final regs	N/A	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME certificates (Category I or II)</li> <li>2. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME certificates (Category I)</li> <li>2. CME certificates (Category I) plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME granting organizations</li> </ol>
Requalification-Experience-done under direct supervision	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from residency or training program or mammography facility</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from residency or training program or mammography facility</li> </ol>
Requalification- Education	N/A	<ol style="list-style-type: none"> <li>1. CME certificates (Category I or II)</li> <li>2. Confirming letters from CME granting organizations</li> </ol>	<ol style="list-style-type: none"> <li>1. CME certificates (Category I)</li> <li>2. Confirming letters from CME granting organizations</li> </ol>

# Radiologic Technologist

## 21 CFR 900.12(a)(2)(ii)

*Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to*

- (A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;*
- (B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and*
- (C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams;*

Question: Is there a specific amount of training or number of mammograms of breast implant patients that the technologist must perform under direct supervision prior to performing these studies independently?

Answer: Although there are no requirements referable to implant training for those radiologic technologists whose starting dates under MQSA are before the effective date of the final regulations (April 28, 1999), FDA recommends that all radiologic technologists have training specific to the imaging of patients with breast implants.

For those radiologic technologists whose starting dates are on or after April 28, 1999, implant specific training is required; however, there is no specific amount of training or minimum number of breast implant patients that must be completed under direct supervision before performing mammographic examinations independently.

Question: Must the technologist complete the 40 hours of training prior to performing the 25 exams under direct supervision?

Answer: No. The time spent performing the examinations can be part of the 40 hours of training (see next question).

Question: What is an acceptable method for documenting the 40 contact hours of documented training specific to mammography?

Answer: The training program or facility providing the training should provide a signed letter(s) or other document(s) on official letterhead indicating that the trainee acquired at least 40 hours of training specific to mammography. The letter(s) or document(s) should include the following:

1. a statement that the training included breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants and, at least 8 hours in each mammographic modality used by the technologist during the training.
2. a statement that the trainee performed at least 25 examinations under the direct supervision of a qualified radiologic technologist.

3. the inclusive dates when the training was given.
4. the name of the individual(s) supervising the performance of the 25 exams.
5. the signature of a responsible official of the facility or training program.

Training programs or facilities can include the actual time spent performing supervised examinations toward the 40 hour total. As guidance, however, no more than 12.5 hours of the required 40 should come from performing examinations. If training was obtained from more than one entity, each entity must provide its own letter documenting those areas that it covered. The total hours from all the letters must meet the requirement.

An example of acceptable documentation could read as follows:

#### OFFICIAL LETTERHEAD

During the dates [INCLUSIVE DATES], [NAME] received at least 40 contact hours of training specific to mammography, including breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants, and at least 8 hours in each mammographic modality used by the technologist during the training. The training included the performance of 25 examinations under the direct supervision of [NAME(S) OF QUALIFIED SUPERVISOR(S)].

#### SIGNED BY RESPONSIBLE OFFICIAL

#### **21 CFR 900.12(a)(2)(iv)(A)**

*Continuing experience requirements. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.*

Question: When is the earliest a facility can be cited for using a radiologic technologist who has failed to meet the continuing experience requirement? When does a radiologic technologist need to start keeping records documenting this requirement?

Answer: A facility will not be cited for this requirement before June 30, 2001, and then only if the radiologic technologist has had at least 24 months since meeting his or her initial requirements.

The radiologic technologist could begin keeping records documenting continuing experience from June 30, 1999, or the date he or she completed the initial requirements, whichever is later. However, FDA recommends that technologists currently in the field or their facilities begin keeping these records even before June 30, 1999. This will allow time to "work the bugs" out of their recording system and/or to identify situations in which workloads may have to be adjusted to meet the requirement before FDA begins citing facilities for failure to meet the requirement.

Question: What are acceptable forms of documentation for demonstrating that the technologist's continuing experience requirement has been met?

Answer: It will generally be sufficient if the technologist's file contains a letter, table, or printout from each facility at which he or she performs mammography examinations, signed by a responsible facility official. The document should state that the technologist has performed a given number of examinations at that facility in a given time period.

It is assumed that these numbers are based upon more extensive records, such as facility logs, that can be reviewed if there are any questions. The facility logs themselves can then be used as documentation. However, the provision of summary letters, tables, or printouts will speed up the inspection process and rarely will the more detailed records be requested.

FDA recommends that these numbers be provided and updated on at least a quarterly basis. Facilities that plan to use the date of inspection as the end of the 24 months may wish to update them more frequently, perhaps monthly, to minimize the effort needed at the last minute in preparing for an inspection.



## ACCEPTABLE DOCUMENTS FOR RADIOLOGIC TECHNOLOGISTS

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State Licensure	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>
Board Certification (ARRT or ARCRT)	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>
Initial Training (~40 hours-interim regs) (40 hours-25 supervised exams-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter or other document from training program</li> <li>3. CBU certificates</li> <li>4. Letter or other document confirming in-house or formal training</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CBU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Approved courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CBU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> </ol>
Initial Mammography Modality Specific training-8 hours-final regs	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Mammography Modality Specific CBU certificates</li> <li>3. CBU certificates plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CEU granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CBU certificates</li> <li>2. CBU certificates plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CBU certificates</li> <li>2. CBU certificates plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Experience (200/24 months-final regs)	N/A	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from training program or mammography facility</li> </ol>
Continuing Education (15 CMB/36 months)	N/A	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Formal training courses</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Formal training courses</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Mammographic Modality Specific Education-final regs	N/A	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CBU certificates</li> <li>2. CBU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CBU certificates</li> <li>2. CBU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Requalification-Experience-final regs-done under direct supervision	N/A	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from training program or mammography facility (done under direct supervision)</li> </ol>
Requalification- Education	N/A	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>

## Medical Physicist

### 21 CFR 900.12(a)(3)

*All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:*

### 21 CFR 900.12(a)(3)(i)

#### *Initial Qualifications*

- (A) *Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and*
- (B)
  - (1) *Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;*
  - (2) *Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and*
  - (3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section;*

### 21 CFR 900.12(a)(3)(ii) Alternative Initial Qualifications

- (A) *Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and*
- (B) *Prior to the April 28, 1999, have:*
  - (1) *A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,*
  - (2) *Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and*
  - (3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.*

Question: Can a mammography unit survey at a non-certified facility count toward the initial experience requirement?

Answer: Only mammography unit surveys of equipment currently regulated by MQSA in a certified facility (or a facility in the process of becoming certified) or of similar equipment in a VA facility can be counted toward the initial experience requirement.

Question: What is the conversion factor used to convert quarter hours to semester hours?

Answer: The conversion factor between quarter hours and semester hours is 1.5:

Example: 15 quarter-hours are equivalent to 10-semester hours: Quarter hours/1.5 = Semester hours ( $15/1.5 = 10$ ) or;

Example: 10-semester hours are equivalent to 15-quarter hours: 1.5 X Semester hours = Quarter hours ( $1.5 \times 10 = 15$ )

Question: What are acceptable methods for documenting medical physicist initial and continuing experience?

Answer: Although the survey reports themselves (original, copy or coversheet from the report) can be used as documentation, in general a summary document, such as a letter or memorandum from the facility where the survey was performed or from the physics company providing the service, will be sufficient. The letter should be on official facility or company letterhead and should indicate the number of facility and/or unit surveys performed, the dates on which they were performed, and be signed by either a responsible official of the facility or physics company providing the service, or by the person providing the direct supervision.

It is assumed that the summary documentation is based upon the survey reports and that these could be examined if need be. However, a facility need not keep on file reports of surveys performed by their physicist at other facilities as secondary documentation of the type described above ordinarily will be sufficient for evaluating the physicist's experience.

Question: What are the required minimum qualifications for the supervisor of an individual who is performing surveys to meet the initial experience requirement or to requalify after failing to meet the continuing experience requirement?

Answer: All surveys performed to meet the initial experience and requalification requirements for the medical physicist must be performed under the direct supervision of a medical physicist who meets all the initial qualification and continuing qualification requirements (described in 900.12(a)(3)(i) and (iii)). NOTE: Medical physicists who qualify under the alternative initial qualification route, section 900.12(a)(3)(ii), cannot provide supervision of surveys performed for the purpose of meeting the initial experience requirement or reestablishing the continuing experience requirement.

Question: What are the minimum qualifications for an individual providing the required initial contact hours of training in conducting surveys of mammography facilities to physicists?

Answer: An individual providing the required initial contact hours of training in conducting surveys of mammography facilities must be a **qualified instructor** as described in 900.2(oo).

Question: Can the performance of facility and unit surveys count toward the survey training contact hours requirement? Must the surveys be done under the **direct supervision** of a qualified medical physicist?

Answer: Time spent in the actual performance of surveys can be used to meet the survey contact hours requirement. As guidance, however, no more than four hours for each facility survey and two hours for each unit survey should be counted toward the required total hours of training. In order to count toward the survey training contact hours requirement, surveys performed after April 28, 1999 must be under the direction of a **qualified instructor**. If these surveys are also being used to meet the initial experience requirement, they must be done under the **direct supervision** of a medical physicist who meets all the requirements of 21 CFR 900.12(a)(3)(i) and (iii). This means that in the typical initial qualifications (Master) situation, surveying one facility and a total of ten units meets both the initial contact hours of specialized training and the initial experience requirements. In the alternative initial qualifications (Bachelor) situation, surveying one facility and a total of 20 units meets both the initial contact hours of specialized training and the initial experience requirements.

**21 CFR 900.12(a)(3)(iii)(B)**

*Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.*

Question: When is the earliest a facility can be cited for using a medical physicist who has failed to meet the continuing experience requirement? When does a medical physicist need to start keeping records documenting this requirement?

Answer: A facility will not be cited for this requirement before June 30, 2001 and then only if the medical physicist has had at least 24 months since meeting his or her initial requirements.

The medical physicist could begin keeping records documenting the continuing experience from June 30, 1999 or the date he or she completed the initial requirements, whichever is later. However, FDA recommends that physicists currently in the field or their facilities begin keeping these records even before June 30, 1999. This will allow time to "work the bugs" out of their recording system and/or to identify situations in which workloads may have to be adjusted to meet the requirement before FDA begins citing facilities for failure to meet the requirement.

Question: If two or more medical physicists perform an annual physics facility survey or unit survey can each count it towards meeting their continuing experience requirement?

Answer: Section 900.12 (e)(9) requires that the annual medical physicist facility survey include:

- a) Performance of the annual tests and the phantom image test
- b) Evaluations of the results of all QC tests conducted by the facility and of any corrective actions taken

If only part (a) of the facility survey as described above is performed, the survey can be counted as a unit survey only.

Section 900.12(e)(9) states that each survey be performed by an individual. FDA believes that two medical physicists cannot jointly (simultaneously) perform a survey on a mammography unit or QC records and gain adequate hands-on experience to be counted toward the continuing experience requirement. However, two or more physicists can perform separate surveys individually at different times on the same unit and/or QC records and count it towards the requirement.

The one exception that FDA recognizes is if a trainee or requalifying physicist performs a unit or facility survey under direct supervision. If such supervision includes both parts (a) and (b) above, both the supervisor and supervisee may receive credit for one facility survey. If only part (a) is performed under direct supervision, then the supervisor and supervisee both may receive credit for one unit survey. Only one trainee or requalifying physicist can be supervised at any one time.

Question: Can a mammography unit survey at a non-certified facility count toward the continuing experience requirement?

Answer: Only mammography unit surveys of equipment currently regulated by MQSA in a certified facility (or a facility in the process of becoming certified) or of similar equipment in a VA facility can be counted toward the continuing experience requirement.

Question: What are acceptable methods for documenting medical physicist initial and continuing experience?

Answer: Although the survey reports themselves (original, copy or coversheet from the report) can be used as documentation, in general a summary document, such as a letter or memorandum from the facility where the survey was performed or from the physics company providing the service, will be sufficient. The letter should be on official facility or company letterhead and should indicate the number of facilities and/or unit surveys performed, the dates on which they were performed, and be signed by either a responsible official of the facility or physics company providing the service, or by the person providing the direct supervision.

It is assumed that the summary documentation is based upon the survey reports and that these could be examined if need be. However, facilities need not keep on file reports of surveys performed by their physicist at other facilities as ordinarily secondary documentation of the type described above will be sufficient for evaluation of the physicist's experience.

ACCEPTABLE DOCUMENTS FOR MEDICAL PHYSICISTS

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State Licensure or Approval	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board
Board Certification (ABR or ABMP)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR
Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway)	1. Original/copy of diploma 2. Confirming letter from college or university	1. Original/copy of diploma 2. Confirming letter from college or university	1. Original/copy of diploma 2. Confirming letter from college or university
Initial physics education-final regs (20 semester hours-Master) (10 semester hours-Bachelor)	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics	1. College or university transcripts 2. Confirming letter from college or university 3. Master degree specifically in physics
Survey Training-final regs (20 contact hours-Master) (40 contact hours-Bachelor)	1. Attestation 2. Letter or other document from training program 3. CME/CEU certificates 4. Letter or other document confirming in-house or formal training 5. Training gained performing surveys	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing surveys	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing supervised surveys
Initial Experience-final regs (1 facility-10 units-Master) (1 facility-20 units-Bachelor)	1. Attestation 2. Copy or coversheet of survey 3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Initial Mammography Modality Specific training-8 hours-final regs	1. Attestation 2. Mammography Modality Specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline or syllabus 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline or syllabus 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Experience (2 facilities-6 units/24 months-final regs)	N/A	N/A	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done
Continuing Education (15 CME/36 months)	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses
Requalification-Experience-final regs-done under direct supervision	N/A	N/A	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Requalification- Education	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other formal training courses

## Equipment

### 21 CFR 900.12(b)

- (1) *Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in Sec. 1020.31(f)(3) of this chapter.*
- (2) *General. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to Sec. 1010.2 of this chapter as meeting the applicable requirements of Secs. 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.*

Question: Is there an exemption or "grandparenting" for equipment currently in use?

Answer: No. The final regulations do not include any "grandparenting" provisions for using non-conforming x-ray equipment after the effective dates. You should note that not all equipment and/or equipment quality control requirements become effective on the same date. Equipment that meets all effective requirements may be used until any requirements that it does not meet actually go into effect.

**21 CFR 900.12(b)(3)** *Motion of tube-image receptor assembly. (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. (ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.*

Question: Could you clarify what is meant by the statement that the mechanism "shall not fail in the event of power interruption"?

Answer: This means that if the power to the x-ray system is unexpectedly terminated during an examination, the tube-image receptor assembly will not move without operator intervention. This requirement is intended to provide additional safety for the patient in the event of power interruption during an examination and to prevent patient injury that might occur if the assembly moves.

The system must prevent motion until the operator determines that such motion is acceptable. Depending on the circumstances in each facility, the time required for the operator to safely remove the patient from the unit may vary. Therefore, the length of time required for the system to remain locked in place will also vary. However, removing the patient from the unit can usually be accomplished in a minute or less. Note: systems that lack built-in mechanisms to prevent unintended gantry motion may meet the requirement using external battery backup or mechanical mechanisms that prevent unintended motion for the amount of time it takes to remove the patient from the machine.

Question: What is meant by the term "power interruption?"

Answer: Power interruption in this context means interruption of external electrical power to the mammography unit. It does not refer to internal system failure.

Question: What motion requirements must the tube-image receptor assembly meet?

Answer: There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power interruption.

Question: How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)?

Answer: The amount of acceptable motion depends on the circumstances in each facility and should be evaluated on an individual basis. The intent of this regulation is to assure patient safety during power interruptions. Facilities should evaluate their machines to determine if the amount of gantry motion during power interruptions is sufficient to allow their typical patient to fall, be twisted, or be pulled from the position that they were placed in by the technologist to such an extent that injury could occur. If such injury could reasonably occur, the regulation has not been met.

**21 CFR 900.12(b)(4)(i)**

*Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.*

Question: Does the term "image receptor" refer to the film, the cassette or the bucky (cassette holder)?

Answer: In screen-film mammography, the term "image receptor" refers to the film, or to pre-selected portions of it in cases where such pre-selection means are provided.

**21 CFR 900.12(b)(4)(ii)**

*Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.*

Question: Our mammography unit has a single image receptor holder that can accommodate both the 24 X 30 cm and 18 X 24 cm image receptors, but has only one size grid. Is that acceptable?

Answer: No. Each mammography system must be equipped to allow operation with both referenced image receptor sizes AND be provided with moving grids matched to each image receptor size provided with the system. Having a system equipped with only a single size moving grid, even if the device is capable of accepting both size cassettes, would not meet the requirements.

**21 CFR 900.12(b)(4)(iii)**

*Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.*



Question: We perform magnification using only the 18 X 24 cm image receptor. Do we have to show that all our other image receptor sizes also meet the magnification requirements?

Answer: No. However, each image receptor size used for magnification must meet the requirements of 900.12(b)(4)(iii), 900.12(b)(6)(ii), and 900.12(e)(5)(iii). Two of these [900.12(b)(4)(iii) requiring such systems to be capable of operating with the grid removed from between the source and the image receptor and 900.12(b)(6)(ii) requiring the system to provide at least one magnification from the range of 1.4 to 2.0] can be considered to be image receptor size dependent. That means that if the facility only performs magnification with one image receptor size, the requirements need be met for only that size image receptor. If the facility performs magnification using multiple sizes of image receptors, then it must meet the requirements with each size receptor used for magnification. The third requirement relating to the system resolution under 900.12(e)(5)(iii) is not usually significantly affected by image receptor size.

#### **21 CFR 900.12(b)(5)**

*For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.*

Question: Who is responsible for performing the light beam test? How often should it be tested and by what method?

Answer: The regulations do not specify a frequency or designate a specific individual to perform testing for the light illuminance requirement. However, the facility is responsible for ensuring the mammography equipment meets MQSA requirements. Such conformance would be verified under the equipment evaluation performed when the equipment is initially placed in service and should be verified periodically throughout its useful life. The verification period should be established with reference to the manufacturer's maintenance specifications and the use considerations (wear and tear) unique to the facility. Anytime the facility or its personnel become aware of suspected problems with the equipment through its use or normal visual checks, the conformance of the equipment should be checked and repair or replacement should be achieved within the times specified under 900.12(e)(8)(ii) but always within 30 days of verifying the problem. Manufacturers may specify procedures and frequency for testing the light illuminance in their maintenance instructions and adherence to these recommendations should normally be adequate; however, the responsibility for compliance still remains with the facility.

Some recommended testing specifications for the average illuminance are found in 21 CFR 1020.31(d)(2)(ii), where it states "The average illuminance shall be based upon the measurements made in the approximate center of each quadrant of the light field." The test must be conducted at the maximal SID or one meter, whichever is less, and should compensate for the ambient light usually present during clinical examinations. Instrumentation used should be appropriate for the purpose. Since this might require special test equipment, FDA suggests that the facility add it to the list of items to be examined by the physicist during the survey.

Question: Is there any specified minimum or maximum SID?

Answer: No. The final MQSA regulations do not limit either the maximum or minimum SID of mammographic x-ray systems.

**21 CFR 900.12(b)(6)(i)**

*Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.*

Question: Must all mammographic units have magnification capabilities?

Answer: The requirement to provide magnification capabilities is limited to those units used to perform noninterventional problem solving mammography. The requirement does not apply to units used only for normal screening procedures. "Noninterventional problem solving mammography" means noninvasive mammographic procedures requiring techniques beyond those used in standard screening of asymptomatic patients.

Question: We are a screening facility that schedules only asymptomatic patients for mammography. Our equipment cannot perform magnification. Are we permitted to perform additional views on patients who unexpectedly report an abnormality or area of concern at the time of the study or who have an abnormality detected during the screening mammogram, or must we refer such patients to another facility that has magnification capabilities?

Answer: If an abnormality or area of concern is unexpectedly reported (for example, by the patient) at the time of the examination or detected on a screening mammogram, facilities are permitted to perform additional views during this examination, that, in their judgement, may help clarify and further characterize the finding (as benign or malignant) or eliminate it as normal overlapping parenchymal structures. Such additional views may include, for example, repeat standard views, spot compression, rolled, or exaggerated views. If, however, the facility decides that a magnification view is necessary for the work-up of the case, but does not have this capability, the patient should be referred to a facility that does have magnification capability.

Facilities should have guidelines for adequately addressing such situations that unexpectedly arise at the time of the study, within their standard operating procedures. Please note that this guidance applies only to those situations in which facilities become aware of unexpected abnormalities or areas of concern, either reported at the time of the study or detected on a screening mammogram. Facilities without magnification capability should not knowingly schedule patients requiring noninterventional problem solving mammographic procedures.

**21 CFR 900.12(b)(8)(i)**

*Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.*

Question: Is power driven compression required once the final regulations go into effect on April 28, 1999?

Answer: No. Power driven compression will not be required until October 28, 2002.

**21 CFR 900.12(b)(8)(ii)(B)**

*Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.*

Question: Who is responsible for performing the compression paddle deflection test? How often should this test be performed and by what method?

Answer: The regulations do not specify a frequency or designate a specific individual to perform testing for this requirement; however, the facility is responsible for ensuring the mammography equipment meets MQSA requirements. FDA has left both the test procedures and frequency to the discretion of the facility. Such conformance would be verified under the equipment evaluation performed by the medical physicist when the equipment is initially placed in service or when there is a major repair involving this component. It should also be verified periodically throughout its useful life. The verification period should be established with reference to the manufacturer's maintenance specifications and the use considerations (wear and tear) unique to the facility. If the excessive deflection of the compression paddle is identified during an equipment evaluation, it must be repaired before the unit is used on patients. If the facility identifies the problem at any other time, it should be repaired as soon as possible because this problem may compromise clinical image quality. Manufacturers may specify procedures and frequency for testing the compression paddles in their maintenance instructions and adherence to these recommendations should normally be adequate; however the responsibility for compliance still remains with the facility.

One acceptable method for performing the compression paddle deflection test is:

1. If the mammographic unit does not have a read-out of compression force, cover the bucky with a towel and place a bathroom scale on the towel.
2. In order to prevent measuring deflection of the image receptor support (bucky) or the scale, place a support plate on top of the scale or directly on the towel if a scale is not used. The support plate should be made of a rigid material (e.g., acrylic sheet) that is large enough to completely cover either the scale or bucky.
3. Place the test object on the support plate with its base along the chest wall edge of the compression plate. Examples of test objects include: compressible foam materials (e.g. T-200 Minicel foam (10 X 18 cm for the 18 X 24 cm paddle and 14 X 22 cm for the 24 X 30 cm paddle, thickness of 4 to 6 cm) or tennis or rubber balls taped together in the shape of an equilateral triangle (3 balls for the 18 X 24 cm paddle and 6 balls for the 24 X 30 cm paddle)
4. Apply a compression force of 111 newtons (25 pounds).
5. Measure the distance of each corner of the paddle from the support plate.
6. Subtract the smallest distance from the largest distance to determine the deflection. The difference must be 1.0 cm or less to pass the test.

Paddles designed not to be flat and parallel to the breast support table during compression should not be evaluated using the procedure described above, but rather must meet the manufacturer's design specifications and maintenance requirements.

**21 CFR 900.12(b)**

- (14) *The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.*
- (15) *Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.*

Question: Are there any regulations regarding viewbox luminance?

Answer: No. The final MQSA regulations do not address the viewbox performance.

Question: Our mammography exams are interpreted off-site. Do we need to have a viewbox, hot light, and masking materials on-site?

Answer: No. Facilities are required to have these items where the exams are interpreted, but are not specifically required to have them where the exams are produced. However, FDA recommends that the above items be provided to the technologists as an aid in performing their duties.

## Medical Records

### 21 CFR 900.12(c)(1)(iv)

*[The report shall contain] Overall final assessment of findings, classified in one of the following categories:*

- (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);*
- (B) "Benign:" Also a negative assessment;*
- (C) "Probably Benign:" Finding(s) has a high probability of being benign;*
- (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;*
- (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;*

### 21 CFR 900.12(c)(1)(v)

*In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and*

### 21 CFR 900.12(c)(1)(vi)

*Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.*

Question: Is it necessary to include an assessment code (e.g. 0, 1, 2, 3, 4, 5 or N, B, P, S, M, A), in addition to the assessment category, on all mammography reports? Is there a specific reporting format required?

Answer: The answer to both questions is "No." In order to promote consistency and clarity in the interpretation of mammograms, the final regulations require that each mammographic report include an overall final assessment of the mammography examination, classified into one of the following six categories: Negative, Benign, Probably Benign, Suspicious, Highly Suggestive of Malignancy, and Incomplete: Need additional imaging evaluation. While the final assessment findings must not vary from these categories and must be stated as written above, limited flexibility is allowed for further description as long as it doesn't change the meaning of the category. The following are considered equivalent to the wording listed in the final regulations and are acceptable final overall assessments.

Negative

Negative Mammogram

Benign

Benign Finding, Benign Findings, Benign Abnormality, Benign Abnormalities, Benign Mammogram

Probably Benign

Probably Benign Finding, Probably Benign Findings, Probably Benign Abnormality, Probably Benign Abnormalities, Probably Benign- Short Interval Follow-up Suggested, Probably Benign Finding - Short Interval Follow-up Suggested, Probably Benign Mammogram

Suspicious

Suspicious Finding, Suspicious Findings, Suspicious Abnormality, Suspicious Abnormalities, Suspicious for Malignancy, Suspicious of Malignancy, Suspicious Abnormality - Biopsy Should Be Considered, Suspicious Finding - Biopsy Should Be Considered, Suspicious Mammogram

Highly Suggestive of Malignancy

Highly Suggestive for Malignancy, Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

Incomplete: Need Additional Imaging Evaluation

Incomplete: Needs Additional Imaging Evaluation, Incomplete: Additional Imaging Evaluation Needed, Incomplete: Need Additional Imaging Evaluation- Comparison with Prior Studies, Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete BIRADS assessment category), Incomplete Mammogram: Need Additional Imaging Evaluation

There is no requirement that any specific assessment code be assigned to these assessments. Also, there is no specific reporting format required for the report, apart from the requirement that an overall assessment category be included within it.

Question: If there is more than one lesion identified on the mammographic examination, do I need to have a final assessment category for each lesion or just one assessment for the entire mammographic examination?

Answer: One overall assessment category for the entire mammographic examination is required, and it should be based on the most suspicious lesion or finding. However, individual assessments for other lesions, along with recommendations for their management, may also be included in the report.

Question: If a facility issues an "addendum" or "comparison" report after the initial mammography report has already gone out, are these reports required to have an overall final assessment category? Must the "addendum" or "comparison" report also be provided to the referring health care provider and the patient, even if there is no change in the final assessment category or recommended course of action?

Answer: Yes to both questions. The report issued after additional testing that is covered under MQSA (e.g., coned, repeat, magnification views) or following comparison with old films should reflect the final assessment category for the case following these additional tests or comparison studies. A report of this nature must be communicated to the referring health care provider or the self-referred patient, just as any other report would be. In addition, a lay summary of the "addendum"

or “comparison” report sent to the health care provider (or self-referred patient) must be provided to all patients, even if there is no change in the final assessment category or recommended course of action. For the specific case where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change would satisfy the requirement. If the “addendum” merely stated that the referring health care provider had been notified of the results of the patient’s examination, the addendum lay summary could be a simple statement informing the patient of that fact.

Question: A facility performs non-mammographic breast imaging studies on the same day as the mammographic examination. Must the facility issue a separate mammography report with its own final assessment category and recommendations, or can the facility issue a combined report whose final assessment category and recommendations represent the overall assessment of all the breast imaging studies performed that day?

Answer: The facility has the option of issuing either separate or combined reports.

#### **21 CFR 900.12(c)(2)**

*Communication of mammography results to the patient.* This section of the regulations has been superseded by the Mammography Quality Standards Reauthorization Act of 1998 which requires that a summary of the written report shall be sent directly to all patients in terms easily understood by a lay person.

*(i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.*

*(ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.*

Question: Does a facility have to accept self-referred patients?

Answer: Neither MQSA nor the final regulations require a facility to accept self-referred patients (facilities should check their obligations under their State requirements). However, if a facility does accept self-referred patients, it must send both the mammography report and a lay summary to the patient. It must also have a system to refer such patients to a health care provider when clinically indicated.

Question: What is the difference between “self-referred” and “self-requesting” patients and how does this affect what types of reports these patients receive?

Answer: “Self-referred” patients are those who come for mammography, but have no health care provider, or who decline a health care provider, or for whom the provider declines responsibility.

“Self-requesting” patients are those who come for mammography on their own initiative, but are able to name a health care provider (or accept a health care provider offered by the facility) who accepts responsibility for that patient’s clinical breast care. These self-requesting patients should be treated the same as referred patients. Please note that in the event the health care provider declines to accept

the mammography report from the facility, the latter should treat the patient as if she/he were self-referred.

Self-referred patients shall receive the written mammography report, in addition to a written lay summary. Self-requesting patients shall receive the same communication of results as referred patients.

Question: Must lay summaries of the "addendum" or "comparison" medical report be provided to all patients, even if there is no change in the findings or recommended course of action?

Answer: A lay summary of the "addendum" or "comparison" medical report must be provided to all patients even if there is no change in the findings or recommended course of action. For the specific case where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change would satisfy the requirement. If the "addendum" merely stated that the referring health care provider had been notified of the results of the patient's examination, the addendum lay summary could be a simple statement informing the patient of that fact.

Question: A facility performs non-mammographic breast imaging studies on the same day as the mammographic examination. Must the facility provide the patient a separate mammography lay summary, or can the facility provide a combined lay summary that represents the overall results and recommendations for all the breast imaging studies performed that day?

Answer: The facility has the option of providing either a separate mammography lay summary or a combined lay summary. FDA recommends that, where feasible, the facility provide a combined lay summary, so as to give the patient the most complete and useful information.

Question: Our facility currently uses a computerized telephone system for communicating mammography results to our patients. Will this system meet the patient communication requirements under the final regulations?

Answer: A computerized telephone system cannot be used in place of a written system for communicating mammographic results to patients.

**21 CFR 900.12(c)(4)(i)**

*Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and*

**21 CFR 900.12(c)(4)(ii)**

*Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;*



Question: A facility ceases operations and closes its doors. What actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?

Answer: When a facility ceases operations and closes its doors, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;
2. Return its facility certificate to its certifying body. For facilities certified by FDA, the certificate should be mailed to P.O. Box 6057 Columbia, MD 21045-6057;
3. Notify its State radiation control program;
4. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or to the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. Facilities should check with State or local agencies to determine if their requirements are more stringent.

If the option in number 4 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Question: What documentation should I get when a patient, or an individual acting on behalf of the patient, or the patient's physician requests the release of the patient's records? How long should I keep the documentation?

Answer: Facilities should request that patients, physicians, or individuals acting on behalf of patients sign a release form, or submit a written release request; however, if the facility chooses to accept oral transfer requests, a notation should be made in a log. Other documentation may also be possible. Facilities should check to see if State or local laws related to release of records require additional documentation.

The documentation should be retained for at least as long as the facility would have had to keep the patient's mammograms.

**21 CFR 900.12(c)(4)(iii)**

*Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.*

Question: What are appropriate charges for the transfer of mammographic records? Can I include the cost of making copies of the films?

Answer: Appropriate charges for transfer of mammographic records could include items such as administrative time costs incurred in logging-in the request, retrieving the mammography films and reports, having the patient sign a release, packaging and mailing charges for the materials, and photocopying costs incurred in making copies of reports.

Facilities may, but are not required by MQSA to, make copies of the mammographic films. If these copies are requested by the patient or are mandated by State regulations, then the cost of making the copies can be charged to the patient. If the facility wishes to keep copies for its own benefit, the cost cannot be charged to the patient.

If requested by the patient, facilities must produce documentation (e.g., itemized bill) that shows the charges do not exceed the costs associated with this service.

#### **900.12(c)(5)**

*Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:*

- (i) Name of patient and an additional patient identifier.*
- (ii) Date of examination.*
- (iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with Sec. 900.3(b) or Sec. 900.4(a)(8) shall be used to identify view and laterality.*
- (iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.*
- (v) Technologist identification.*
- (vi) Cassette/screen identification.*
- (vii) Mammography unit identification, if there is more than one unit in the facility.*

Question: Do I have to label all my films with the mAs, kVp, compressed breast thickness or compression force used?

Answer: No. The final regulations do not require that mammographic images be labeled with mAs, kVp, compression force or compressed breast thickness. However, a facility has the option to include this information on the film if they believe it beneficial.

Question: Would the use of stickers meet the requirements of film labeling as stated in 900.12(c)(5)?

Answer: Use of stickers, and other forms of permanent and legible markers, would meet the requirements of film labeling as stated in 900.12(c)(5).

Question: What is meant by "cassette/screen identification" in 900.12(c)(5)(vi) and does the type of screen need to be identified on each film?

Answer: The regulations refer to the cassette/screen as a combination, because in today's mammography practice, the screen is typically supplied by the manufacturer as an integral part of the

cassette. Hence, to meet the requirement that the cassette/screen be identified on the patient image, it is sufficient for the facility to identify the cassette alone. This may be done by placing the marker or ID so that it may be imaged on the film. Care should be taken so that the marker does not obscure patient anatomy.

## **Quality Assurance - General**

### **21 CFR 900.12(d)(1)(i)**

*Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.*

Question: Our mammography exams are interpreted off-site. Do we need to have a lead interpreting physician on-site?

Answer: The requirement that a facility have a lead interpreting physician is still applicable, but the physician need not be on-site.

### **21 CFR 900.12(d)(1)(iv)**

*Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.*

Question: Does the quality control technologist have to be a qualified mammography technologist?

Answer: Yes. Section 900.2(pp) requires that the quality control technologist meet the qualifications for performing mammography examinations.

## **Quality Control (QC) Tests - General**

Question: Why hasn't FDA specified the protocols for performing QC tests?

Answer: In the final regulations, FDA has focused primarily on the performance aspects of the quality control testing, in contrast to the interim regulations, which included a complete set of procedures through referencing the ACR manuals. As a result, the agency has refrained from providing extensive detailed requirements or descriptions of test procedures.

The regulations specify the required QC test criteria and outcomes (tests to be done, frequency, and especially the action limits to be met). FDA's approach gives facilities the flexibility to use

procedures that best enable them to meet the requirements. Facilities may continue to use procedures found in current manuals as long as they are consistent with the final regulations. Besides the test methodologies, the facilities can also use their own formats or those of appropriate manuals (e.g., charts, tables) for documenting test results.

Question: How often must the densitometer and sensitometer be calibrated?

Answer: There are no regulatory requirements for calibrations of these devices. FDA encourages the facility to follow the manufacturer recommended calibration procedures for such devices.

Question: When performing a physics survey or equipment evaluation on a unit with multiple target/filter combinations, what tests or measurements must be performed for each combination?

Answer: For a unit with multiple target/filter combinations, the following tests must be performed for each clinically used target/filter combination:

- Focal spot condition (for different target materials (tracks) only)
- X-ray field/light field/image receptor/compression paddle alignment (for different target materials (tracks) only)
- Beam quality and half-value layer
- Automatic exposure control performance
- System artifacts

Question: I have been following the ACR manual and have used an optical density range of 0.7-0.8 when doing my screen-film contact test. The film manufacturer recommends that I use a higher optical density. What should I use under the final regulations?

Answer: The final regulations do not reference a specific manual giving facilities flexibility to use procedures that best enable them to meet the requirements. In this specific case, the facility may follow the manufacturer's recommendation, their medical physicist's recommendation, or an appropriate manual in performing the screen-film contact test or any other QC test.

Question: If there are several acceptable methods for testing performance of a QC requirement and the item being tested passes by one, but not all, the methods, does the item still meet the requirement?

Answer: Yes, as long as the required QC test criteria and outcomes (tests to be done and especially the action limits to be met) are satisfied.

Question: A facility is using more than one type of screen-film combination. Must it perform the QC tests separately for each combination used?

Answer: It depends. For the majority of the QC tests, the type of screen-film combination used in the test is irrelevant to the test outcome. However, for the following QC tests, the regulations spell out specific requirements:

1. System Resolution - must be measured for each screen-film combination used at the facility with its corresponding unit(s).
2. Phantom Image and Dose – each of these must be conducted for each screen-film combination clinically used for the standard breast.

Note that the phantom image test applies to both the weekly QC and the annual test conducted by the medical physicist as part of the survey report. If only one combination is routinely used for the standard breast and the other combination is used for non-routine examinations of the standard breast, FDA recommends that the dose and phantom image QC tests also be conducted for the other combination, because the outcome of both tests is heavily influenced by the film-screen combination used.

Note that testing for the uniformity of screen speed must be conducted for all screens and cassettes respectively. Hence, by default, it includes all types of screens used, but this does not preclude performing this test with only one type of film. System artifacts must be performed for each cassette size.

Question: How should facilities document performance of the required QC tests to comply with the regulations?

Answer: Performance of the required QC tests must include clear and legible documentation. The documentation must include the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and the corrective actions taken and their results. The data and results should be properly charted or tabulated. Facilities may consult any appropriate quality control manual for examples of charts and tables or establish their own format for documenting the test data and the results.

#### **21 CFR 900.12(e)(1)**

*Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.*

- (i) The base plus fog density shall be within + 0.03 of the established operating level.*
- (ii) The mid-density shall be within <plus-minus> 0.15 of the established operating level.*
- (iii) The density difference shall be within <plus-minus> 0.15 of the established operating level.*

Question: Must a facility perform the daily processor QC tests on days when mammograms are performed but not processed?

Answer: No. Facilities are required to perform these tests only on the days they process mammograms. However, FDA recommends that facilities that routinely process mammograms less than 5 days/week perform the daily processor QC tests on additional days. The additional tests can

provide the facility more information to predict trends and thereby identify and correct problems earlier.

Question: We have a separate processor that we only use to make mammography copies. Are there any MQSA requirements that this processor has to meet?

Answer: No. There are no MQSA requirements for processors that are used only for copying mammograms. However, if such a processor is also used to process original mammograms, then you must perform processor QC on it and assure that it is in control before you use it to process mammograms.

**21 CFR 900.12(e)(2)**

*Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.*

- (i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.*
- (ii) The optical density of the film at the center of the phantom image shall not change by more than  $\pm 0.20$  from the established operating level.*
- (iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).*
- (iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than  $\pm 0.05$  from the established operating level.*

Question: Under what circumstances should I establish a new baseline optical density (OD) operating level?

Answer: A new baseline OD operating level may need to be established when switching to a new type of film or if the AEC density selector settings in the mammographic unit have been re-calibrated during servicing of the unit. Before changing operating levels, check that there isn't an underlying problem that needs to be corrected. A new level may be established if the interpreting physician(s) has/have made an intentional decision to modify background optical densities of the clinical images. For example, many facilities are choosing to increase film density to take advantage of the film's increased contrast at higher ODs.

Question: Should artifacts be subtracted during the evaluation of the weekly phantom QC test and should the fibers, speck groups and masses be charted separately?

Answer: A facility must follow the criteria established by its accreditation body in scoring weekly phantom images. Facilities accredited by the ACR may wish to review the latest ACR QC manual.

Question: Under the interim regulations, it was required (by referencing the ACR manual) that the "added" test object used to perform the image contrast test be placed on top of the phantom. Will this continue to be a requirement under the final regulations or could the added test object be located in some other position?

Answer: It is the intent of the regulation that the test object be placed on top of the phantom in a consistent, and if possible, permanent location in the image area. Consistency in positioning the added test object is necessary to achieve a meaningful operating level density difference between the background of the phantom and the added test object that must not vary by more than  $\pm 0.05$  OD of the established operating level. However, the position of the test object is not specified in the final regulations. If a facility believes it beneficial to place the "added" test object in a different position (e.g., adjacent to the phantom), it will have to assure consistent positioning of the "added" test object, as well as provide the additional x-ray attenuation needed to give a background OD equal to that of the phantom.

## QC Tests - Annual

### 21 CFR 900.12(e)(5)

*Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:*

- (i) *Automatic exposure control performance.*
  - (A) *The AEC shall be capable of maintaining film optical density within  $\pm 0.30$  of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within  $\pm 0.30$  of the average under phototimed conditions can be produced.*
  - (B) *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within  $\pm 0.15$  of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.*
  - (C) *The optical density of the film in the center of the phantom image shall not be less than 1.20.*
- (ii) *Kilovoltage peak (kVp) accuracy and reproducibility.*
  - (A) *The kVp shall be accurate within  $\pm 5$  percent of the indicated or selected kVp at:*
    - (1) *The lowest clinical kVp that can be measured by a kVp test device;*
    - (2) *The most commonly used clinical kVp;*
    - (3) *The highest available clinical kVp, and*
  - (B) *At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.*
- (iii) *Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.*
  - (A) *System Resolution.*
    - (1) *Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.*
    - (2) *The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.*
    - (3) *When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.*
    - (4) *When more than one SID is provided, the test shall be performed at SID most commonly used clinically.*



- (5) *Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.*
- (B) *Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1 in the Federal Register [Vol. 62, N0. 208, page 55990].*
- (iv) *Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2 in the Federal Register [Vol. 62, N0. 208, page 55990]. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.*
- (v) *Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mA's shall not exceed 0.05.*
- (vi) *Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.*
- (vii) *X-ray field/light field/image receptor/compression paddle alignment.*  
Proposed rule change as published in the *Federal Register* on November 5, 1998 (A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than two percent of the SID.
- (B) *If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.*
- (C) *The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.*
- (viii) *Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.*
- (ix) *System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.*
- (x) *Radiation output.*

- (A) *The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.*
- (B) *The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.*
- (xi) *Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:*
  - (A) *An override capability to allow maintenance of compression;*
  - (B) *A continuous display of the override status; and*
  - (C) *A manual emergency compression release that can be activated in the event of power or automatic release failure.*

Question: Is uniformity of screen speed to be evaluated separately for each size or speed class of cassette or combined for all cassettes of all sizes and speed classes?

Answer: The intent of this regulation is to provide the technologist performing the examination reasonable assurance that there will be consistency and reproducibility between the images produced using the same type cassette. However, a facility may use cassettes specifically designed to be of different speeds to deal with various clinical problems. In addition, cassettes of different sizes, even from the same manufacturer, may yield different screen speeds due to differences in design and the use of different types of screens. In those cases where a facility has clearly and permanently identified groups of cassettes of different speeds, has established mammographic technique charts to compensate for the different speed cassettes, and has made these charts available to all their radiologic technologists, the facility can group these cassettes for purposes of the screen speed uniformity test. As long as the difference between the maximum and minimum optical density of all cassettes within a group does not exceed 0.30, the requirement has been met. For any group of cassettes used to image the **standard breast**, the facility must assure that the radiation dose does not exceed the requirement limit of 3.0 milligray (mGy).

Question: Does the condition of the focal spot have to be measured at all possible magnification values?

Answer: The facility is required to evaluate the focal spot condition only for the clinically used magnification factor as close to 1.5 as can be achieved with the system.

Question: What is meant by the term "focal spot condition" and how does it relate to "system resolution"?

Answer: "Focal spot condition" is a general term that was coined to serve as a heading for the section of the regulations that includes tests that yield information on the focal spot. One of these tests involves a measurement of focal spot dimensions, the other assesses the system resolution. The focal spot measurements provide information about focal spot sizes, whereas the system resolution test provides an evaluation of the performance of the entire system (focal spot measurement evaluates only one component of the system). Thus the system resolution is an outcome-based test and has a greater value in image quality evaluation. Therefore, FDA makes the system resolution test mandatory effective October 28, 2002.

The regulations do not prohibit the use of focal spot measurements in addition to the system resolution test. FDA believes if the system resolution test indicates a problem, focal spot measurements should be performed to determine if the focal spot is the cause of the problem. In many cases, the focal spot will not be the cause of the system resolution test failure, and other factors in the imaging chain will have to be evaluated to identify the actual problem.

Question: Where in the x-ray field should focal spot size be measured?

Answer: Under the final regulations, the FDA has provided flexibility to facilities to use procedures that best enable them to meet the requirements. Facilities should be aware that the focal spot size measurement can vary depending on where it is measured in the x-ray field. Therefore, facilities should follow the manufacturer's recommendation or physicist's judgment or any appropriate QC manual for the appropriate procedure to meet the focal spot tolerance limit listed in the regulation.

Question: Has FDA specified a standard method for placement of the high frequency end of the bar pattern when performing the system resolution test?

Answer: No. Facilities are free to determine the placement of the high frequency end of the bar pattern as long as the bars within the pattern remain oriented perpendicular or parallel to the anode-cathode axis.

Question: When measuring light field misalignment, must the misalignment at each edge be within 2% of the SID or is it the total misalignment (both edges) in either the length or width dimension that must be within 2% of the SID?

Answer: The total misalignment (both edges) in either the length or width dimension must be within 2% of the SID.

Question: Radiation output must be measured "at any SID where the system is designed to operate." Does this mean that I must measure the output at all possible SID settings?

Answer: No. Since the maximum SID setting represents the "worst case" scenario, radiation output needs to be measured only at the maximum SID setting.

Question: My facility uses two distinct groups of small sized cassettes of different speed classes to image the **standard breast**. Must annual dose measurements be obtained for both groups of cassettes?

Answer: Yes.

## Medical Physicist's Annual Survey

### 21 CFR 900.12(e)(9)

#### *Surveys.*

- (i) *At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*
- (ii) *The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*
- (iii) *The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*
- (iv) *The survey report shall be sent to the facility within 30 days of the date of the survey.*
- (v) *The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

Question: Must the annual (once a year) physics survey be performed exactly 12 months after the previous one, or is there some flexibility allowed in scheduling the survey?

Answer: The medical physics survey must be performed at least annually (once a year). FDA realizes surveys cannot usually be scheduled exactly on the anniversary date of the previous survey; therefore, an occasional period of up to 14 months is acceptable.

Question: My medical physicist recommended several corrective actions in our physics survey. Will our facility be cited if we do not implement all the recommendations?

Answer: It depends. If your medical physicist recommended that you fix the part(s) of your equipment or practices that failed to meet FDA's requirements, then you will be cited for not implementing those recommendations. You will not be cited for failure to implement recommendations regarding items that are not required in the regulations. If your medical physicist's recommendations concerned problems that he/she thought you may encounter if you did not take action, and if you chose not to implement the recommendations, you should at least document that you considered such recommendations and the reasons you did not implement them.

## Calibration of air kerma measuring instruments

### 21 CFR 900.12(e)(12)

*Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of <plus-minus> 6 percent (95 percent confidence level) in the mammography energy range.*

Question: What are the physicists' responsibilities with respect to the requirement for calibration of their air kerma measuring instruments?

Answer: The physicist must use an instrument that has been calibrated (by the National Institute of Standards and Technology (NIST) or by a laboratory that participates in and has met NIST's proficiency test requirements) within the last two years or since its last repair to an accuracy of +/- 6 percent (95 percent confidence level) in the mammography energy range. The physicist should plan ahead for calibrations so as to provide adequate time for his or her chosen calibration laboratory to complete the work in time.

Question: How should the physicist indicate to the mammography facility that the air kerma measuring instrument has met the requirement?

Answer: The physicist should include the date of the last calibration in the annual physics survey report. The physicist must retain, in his or her records, the documentation (letter, certificate, report, etc.) from the calibration laboratory showing:

1. the date of the instrument's calibration.
2. that the instrument met the required accuracy or if it did not, the correction factors that must be used to bring the measurements within the required accuracy.

Question: A physicist utilizes a calibration laboratory after it has been notified by the National Institute of Standards and Technology (NIST) that it has failed its latest proficiency test. Can those calibrated instrument be used for MQSA evaluations?

Answer: No. Instruments calibrated by a laboratory after the laboratory has been notified that it failed NIST's proficiency test can not be used for MQSA evaluations.

# Mammography Medical Outcomes Audit

## 21 CFR 900.12 (f)(1)

### *General requirements.*

*Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently became known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.*

Question: Must facilities differentiate screening from diagnostic studies when analyzing their medical outcomes audit data?

Answer: No. Although facilities must include all positive mammograms in the audit, they are not required to perform separate analyses for screening and diagnostic examinations. However, it may be in the facility's best interest to perform separate analyses for screening and diagnostic examinations, since the facility may gain important information leading to improvements in mammography quality.

Question: Our radiology practice consists of several separately certified mammographic facilities. Is it permissible to combine our medical outcomes audit for all our facilities, or must it be broken down for each facility?

Answer: The regulations require that each certified facility establish a system to perform a medical outcomes audit analysis for that facility. The mechanics of data collection and analysis do not have to be performed by the individual facility, but may be accomplished by combining the resources of several facilities, pathology registries, or other sources. However, the medical outcomes analysis must be facility specific and must be analyzed (both individually and collectively) for all interpreting physicians at that facility. If physicians read at more than one facility, they may find it beneficial to collectively analyze the data for all the facilities where the physicians interpret. However, this global analysis would not satisfy the requirement that the analysis be facility specific.

Question: Must a facility establish a "system" to identify their false negative examinations?

Answer: No. However, if the facility becomes aware of a false negative examination, they are required to review the mammographic examinations in question and try to obtain surgical and/or pathology information. These cases must be included in the medical audit analyses.

Question: If a facility issues "addendum" or "comparison" reports, do these new reports have to be included in the medical audit?

Answer: If, as a result of the "addendum" or "comparison" reports, the final assessment category of the case is upgraded to "Suspicious" or "Highly suggestive of malignancy", facilities must include it in the medical outcomes audit. If, as a result of the "addendum" or "comparison" reports, the case is

downgraded to "Negative", "Benign" or "Probably Benign", this information must be entered for the original case, and the facility must attempt follow-up to determine if a biopsy was performed in the interim.

## Consumer Complaint Mechanism

### 21 CFR 900.12 (h)

*Consumer complaint mechanism.*

*Each facility shall:*

- (1) Establish a written and documented system for collecting and resolving consumer complaints;*
- (2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;*
- (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;*
- (4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.*

Question: What is an example of an acceptable system for collecting and resolving consumer complaints?

Answer: The MQSA final regulations require facilities to have a written and documented standard operating procedure for responding to consumer complaints. The facility may select its own format. An example of an acceptable system for collecting and documenting the consumer complaint is described below:

1. The facility designates a facility contact person with whom consumers, the accreditation body, and FDA can interact regarding serious consumer complaints. The contact person and other health professionals at the facility develop a clear understanding of the definitions of "consumer," "adverse event," "serious adverse event," and "serious complaint" so all parties are knowledgeable about the requirements of the consumer complaint mechanism.
2. If the facility cannot resolve a complaint to the consumer's satisfaction, the facility provides the consumer with directions for filing serious complaints with the facility's accreditation body. These directions are to be provided in writing.

The facility may wish to post a sign to explain how to file complaints. In this case, the facility could use messages such as, "We care about our patients. If you have comments and/or concerns, please direct them to (the name of the person in the facility who is responsible for complaints)."

This would be in addition to the name and address of the accreditation body, which is listed on the facility's certificate. The facility is required by law to post the certificate prominently in the facility.

3. The facility keeps documentation of the complaint on file for a period of three years from the date the complaint was received. The facility may develop a form to record, at a minimum, the following items concerning "serious complaints": name, address and telephone number of the person making the complaint; date of the complaint; date the serious adverse event occurred; precise description of the serious adverse event (including the name(s) of the individual(s) involved); how the complaint was resolved; and the date the complaint was resolved. This record can be either manual (written) or computerized, depending on the facility's preference.
4. The facility acknowledges the consumer's complaint, investigates the complaint, makes every effort to resolve the complaint, and responds to the individual filing the complaint within a reasonable time frame (these steps can usually be accomplished within 30 days).
5. The facility assures that the complaint and any information regarding the complaint or its followup will be shared only with those needed to resolve the complaint. In addition, facilities should design their complaint procedures to be responsive to the particular needs of the patients they serve. Patients or their representatives may complain in person or in writing.
6. The facility reports unresolved serious complaints to its accreditation body in a manner and timeframe specified by the body. The facility may wish to contact their accreditation body regarding this requirement. For easy reference, facilities may want to keep a separate listing of unresolved serious complaints, with the date of referral, summary and date of response, if any, from the accreditation body. (This would be in addition to the record described in number 3, above).

FDA suggests that facilities analyze the complaints to determine if persistent/recurrent problems exist and use this information to help improve their mammography services.

The primary responsibility for the consumer complaint mechanism is with the facility. However, for complaints that cannot be resolved at the facility, the consumer may choose to report the complaint to the accreditation body or the FDA.

## **Additional mammography review and patient notification**

### **BACKGROUND**

The Food and Drug Administration (FDA) developed this Additional Mammography Review (AMR) guidance to assist FDA officials in determining the appropriate agency response when MQSA inspections show a Level 1 finding for phantom image testing or interpreting physician qualifications. A Level 1 finding represents a deviation from MQSA standards that may seriously compromise the quality of mammography services offered by the facility. FDA has determined that these specific Level 1 findings are indicators that serious quality problems may be present at the facility. An assessment of the quality of mammograms produced by the facility should indicate whether the



equipment problems that resulted in the Level 1 phantom image finding have affected clinical image quality. A Level 1 finding for the phantom image test exists when the score is less than 3 fibers, less than 2 speck groups, and/or less than 2 masses. Regarding interpreting physician qualifications, an assessment of mammograms and mammography reports may indicate whether failure to meet specific personnel standards has affected the quality of mammographic findings.

While this policy only identifies two specific problems that could result in FDA requiring AMR for a facility, there may be other evidence or information that could convince FDA to require AMR. This evidence or information may not be obtained from a routine MQSA inspection, but from another source, such as the facility's accreditation body.

This guidance provides specific criteria to assist the agency in determining the appropriate type and scope of assessment that would be necessary, how and by whom the action should be conducted, and whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and/or accuracy of interpretation of mammograms may have been compromised. In the case of Level 1 inspection findings, FDA may require that the facility undertake an investigation of the impact of these findings on the clinical images produced by the facility or of the interpretations rendered by the interpreting physician.

This policy is effective April 28, 1999, when the authority to require a facility to undergo AMR is also effective. This authority is stated as follows (21 C.F.R. Part 900.12(j)):

*Additional mammography review and patient notification.*

*(1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.*

*(2) If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.*

There are two specific types of AMR identified in this policy. These are AMR Conducted by the Facility (AMRF) and AMR Conducted by the Accreditation Body (AMRAB). Under AMRF, FDA would work with the facility to identify a qualified interpreting physician(s) who would perform the AMR. The physician(s) would be subject to FDA approval. Under AMRAB, the facility's accreditation body would be asked to conduct the AMR.

This policy does not prevent FDA from taking legal actions against facilities, in addition to AMR, where the use of an MQSA sanction may be necessary to compel a facility to comply with FDA regulatory requirements. As an example, FDA may issue a Directed Plan of Correction (DPC) to a facility to address serious problems at the facility. This DPC may require, in addition to specific corrective actions that the facility must take, that the facility undergo AMR and notify patients and/or their referring physicians, in the event mammography quality problems are present that would justify such a notification.

Note: The interpreting physician(s) conducting the image review for AMRF or AMRAB should not have a relationship with the facility, conduct the review when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility. Before the facility's accreditation body (AB) conducts AMRAB, the AB may require reimbursement of their expenses for the AMRAB. In this case, the AB should notify the facility accordingly, including an estimate of the cost to conduct the AMRAB. The AB may also require payment prior to the start of the AMRAB.

## **PHANTOM IMAGE - LEVEL 1 FINDINGS**

### **Criteria - Phantom Image**

#### AMR Conducted by the Facility (AMRF)

If a facility has a Level 1 phantom image finding, but there is no other evidence of serious problems relating to image quality, then it may be asked to conduct AMRF. In the event that a facility refuses to conduct AMRF, FDA may refer the facility to their AB for AMRAB.

#### AMR Conducted by the Accreditation Body (AMRAB)

If a facility has a Level 1 phantom image finding and there is other evidence of serious problems relating to image quality or it refuses to conduct AMRF, then FDA may require the facility to undergo AMRAB. Examples of types of other serious problems are listed below. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts (see note at end of Background section), FDA may require the facility to undergo AMRAB. FDA, in conjunction with the AB, would rely primarily on the following criteria, by themselves or in combination, to evaluate whether quality at the facility may be sufficiently impaired for FDA to require the facility to undergo AMRAB.

- Level 1 finding for phantom image was not due to artifacts and failing phantom image raw score was less than 6.
- Review of phantom images performed by the technologist for the weekly quality control (QC) testing for the time period back to the previous inspection demonstrates more than one Level 1

phantom image failure without corrective action.

- Other Level 1, Level 2, and/or numerous Level 3 findings related to equipment QC testing are detected during the inspection.
- Other indications of quality problems may be present at the facility (examples: prior or pending serious patient complaints to FDA or the State; Level 1 or Level 2 findings or numerous Level 3 findings related to equipment QC testing in the previous annual inspection).

Note: Serious complaint means a report of an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner. Each complaint should be evaluated carefully to assure that information in the complaint is valid.

- FDA determines that the facility would not be able to or is unwilling to undergo AMR conducted by the facility.

## **Procedure for AMR - Phantom Image**

### Evaluation of Inspection Findings and Other Information

1. All phantom image test results at Level 1 must be confirmed through a second review by the MQSA auditor or an FDA MQSA inspector (or by the State, if the State has a thorough phantom image quality assurance (QA) program in place). For those cases where there are no second reviewers in the district or regional office, the Division of Mammography Quality and Radiation Programs (DMQRP) could provide a second review.
2. The district should download the inspection reports (including the detail report containing all of the inspection data) to evaluate all the findings of the inspection. The district should contact DMQRP with their evaluation and determine whether the findings meet the criteria for AMRF or AMRAB. The district would also indicate what arrangements were being made to have a second evaluation of the Level 1 phantom images from the inspection, if not already done.
3. Level 1 finding only: If a facility inspection has a Level 1 finding for phantom image, the district should confirm that the Level 1 finding is correct. FDA should evaluate the findings, along with any other information, including complaints about clinical mammograms, to determine whether AMRF or AMRAB is appropriate.
4. Level 1 finding with other findings and/or complaints: In the event that the facility has a Level 1 finding for phantom image and there are other serious problems or complaints identified with this facility (see examples above), FDA may confer with the AB as to whether the AB should undertake AMRAB.
5. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB about implementation of the AMRAB. The district may send a Warning

Letter to the facility which would indicate that the facility's AB has been asked to conduct AMRAB in response to the findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts, FDA may require the facility undergo AMRAB.

#### **Follow-up Actions by FDA with the Facility**

1. If the conditions are met for AMRF (i.e., there is no other evidence of serious problems relating to image quality), the district should send a Warning Letter to the facility. The letter would require that the facility conduct AMRF in response to the findings. The letter would also indicate that the facility would be responsible for the cost of the AMR.
2. If the facility agrees to conduct AMRF, the district would monitor the progress of the review until completion. The review of images under AMRF could be on-site at the facility or by mail.
3. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB as to whether the AB should undertake AMRAB. The district may send a Warning Letter to the facility that would indicate that FDA had asked the facility's AB to conduct AMRAB in response to the inspection findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts, FDA may require the facility to undergo AMRAB (see note regarding expenses for AMRAB in the background section).
4.
  - a. For both AMRF and AMRAB, the review should cover a sample of mammographic examinations produced using the same equipment (x-ray system and processor) that was tested and found to fail phantom image evaluation during the inspection. The review should be retrospective and start with the last set of mammographic images produced prior to the inspection phantom image test and proceed backward to earlier examinations. The review should concentrate on examinations conducted as close as possible to the date and time of the inspection. The review should encompass the appropriate number of examinations needed to effectively evaluate the impact on mammographic quality of the image quality problems discovered through phantom image evaluation. The review should extend back to the most recent date when the facility's weekly QC phantom images did not show a Level 1 finding.
  - b. If none of the facility's weekly QC phantom images showed a Level 1 finding without corrective action, then the review period should be from the date of inspection back to the date of the last QC phantom image.
  - c. While the size of the sample will vary with the situation, the sample should probably be no smaller than ten percent of the examinations conducted in the time period selected for evaluation.
  - d. In the event that the facility has not performed weekly QC phantom images, the review period

could extend from the date of inspection back to the date of the last medical physicist survey (provided the physicist score was not the equivalent of a Level 1 finding).

- e. In the event that the facility has not performed weekly QC phantom images and the medical physicist survey showed either the equivalent of a Level 1 finding for the phantom image, as scored by the medical physicist, or the phantom image test was not done by the medical physicist, then the period for review could extend from the date of inspection back to the date of the previous inspection.

Note: The decision for the time period covered for the AMR should be based on public health considerations for the patients who were examined.

- 5. The AMR should consist of reviewing a sample of mammograms (or all of the mammograms, if appropriate) from the specified period and, depending on the results of the review, the review may be extended.
- 6. The review of images under AMRAB would be on-site at the facility or by mail, as determined by the facility's AB in consultation with FDA.
- 7. If the results of the AMRF or AMRAB indicate that the quality of mammographic images or interpretations at the facility represent a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). If appropriate, FDA may ask the facility to undertake notification of patients and/or referring physicians. If the facility does not agree or does not have the means to perform a patient notification (PN), FDA would consider other methods of initiating a PN.
- 8. The district and DMQRP should coordinate implementation and monitoring of the notification process.
- 9. If the results of the AMR do not indicate a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary. FDA might require the AB to perform continued close monitoring of this facility. In the case of AMRF, FDA may require the AB to perform its own AMR.

# INTERPRETING PHYSICIAN - LEVEL 1 FINDINGS

## Criteria - Interpreting Physician

### AMR Conducted by Facility (AMRF)

If a facility has a Level 1 finding for interpreting physician qualifications, with no other inspection findings for the physician or other significant evidence that the quality of interpretation of mammograms is compromised, then FDA may ask the facility to conduct AMRF. Currently, facilities may have a Level 1 finding for interpreting physician qualifications if the physician is neither board certified nor has the initial (two or three months) training in mammography and/or never had a valid license to practice medicine.

### AMR Conducted by Accreditation Body (AMRAB)

If a facility has a Level 1 finding for interpreting physician qualifications and has other problems that may relate to the qualifications of the interpreting physician, then the facility may be asked to conduct AMRAB. Some examples of other problems could include complaints regarding the performance of the interpreting physician or other inspection findings relating to the physician's qualifications. In these cases, FDA, in conjunction with the AB, may evaluate whether quality at the facility may be sufficiently impaired for FDA to require that the facility undergo AMR by the facility's AB (AMRAB).

Note: An interpreting physician, who fails to meet the qualifications under the MQSA quality standards, may not continue to read and interpret mammograms independently until he or she has received the necessary training or experience to meet the qualifications.

## Procedure for AMR - Interpreting Physician

### Evaluation of Inspection Findings and Other Information

1. Level 1 finding only: If a physician was not board certified nor had initial training in mammography and/or never had a valid license to practice medicine, the district should confirm that the Level 1 finding is correct. FDA should evaluate the findings, along with any other information, including complaints about the physician, to determine whether AMRF or AMRAB is appropriate.
2. The district should download the inspection reports (including the detail report containing all of the inspection data) to evaluate all the findings of the inspection. The district should contact DMQRP with their evaluation and determine whether the findings meet the criteria for AMRF or AMRAB.

3. Level 1 finding with Level 2 findings and/or complaints: In the event that the facility has a Level 1 finding for a physician and there are other serious problems or complaints identified with this physician (examples could include Level 2 findings for initial and/or continuing qualifications or the AB or FDA has received serious complaints about the quality of the physician's interpretation accuracy (i.e., missed cancers or incorrect interpretations)), FDA may confer with the AB as to whether the AB should undertake AMRAB.
4. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB about implementation of the AMRAB. The district may send a Warning Letter to the facility which would indicate that the facility's AB has been asked to conduct AMRAB in response to the findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts (see note regarding expenses for AMRAB in the background section), FDA may require the facility undergo AMRAB.

Note: Complaints may come from a facility, patient, inspector, or other source. If the AB suspects an interpretation problem may be present, due to complaints or other information, the AB should provide FDA with all the pertinent information in their possession. In the absence of any inspection findings regarding the physician, the AB will conduct follow-up for any complaints received according to its existing complaint procedures.

#### Follow-up Actions by FDA with the Facility

1. If the conditions are met for AMRF (i.e., there is no other evidence of serious problems (findings, complaints, etc.) relating to the physician), the district should send a Warning Letter to the facility. The letter would require that the facility conduct AMRF in response to the findings. The letter would also indicate that the facility would be responsible for the cost of the AMRF.
2. If the facility agrees to conduct AMRF, the district would monitor the progress of the review until completion. The review of images and reports under AMRF could be on-site at the facility or by mail.
3. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB as to whether the AB should undertake AMRAB. The district may send a Warning Letter to the facility that would indicate that FDA had asked the facility's AB to conduct AMRAB in response to the inspection findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts, FDA may require the facility to undergo AMRAB.
4. The AMR may encompass reinterpretation of all films or limit reinterpretation to a random sample of cases and could be either on-site or by mail. In either case, the facility should generate amended reports and notify appropriate physicians and patients of significant differences from original reports. While the size of the sample will vary with the situation, the sample should probably be no smaller than ten percent of the examinations conducted in the time period selected for evaluation.

5. If the results of the AMRF or AMRAB indicate that the interpretation of mammograms at the facility represent a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). If appropriate, FDA may ask the facility to undertake a patient notification (PN) of patients and/or referring physicians, where the initial interpretation may have been deficient. If the facility does not agree or does not have the means to perform a PN, FDA would consider other methods of initiating a PN.
6. The district and DMQRP should coordinate implementation and monitoring of the notification process.
7. If the results of the AMR do not indicate a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary. FDA might require the AB to perform continued close monitoring of this facility. In the case of AMRF, FDA may require the AB to perform its own AMR.